REMARKS

Claims 1, 7, 10, 11, 18-27, 55, 56, 59, and 60 are pending in the present application. Claims 1, 7, 10, 11, 18-27, 55, 56, 59, and 60 have been rejected. Claim 55 has been cancelled without prejudice or disclaimer. Claims 1 and 60 have been amended. Amendments to claim 60 are clerical in nature. Applicants assert that no new matter has been introduced.

Priority

In the Office Action, the Examiner alleged that in order to obtain a priority filing date from an earlier application for a sequence in the subject application (for example, SEQ ID NO: 1), the earlier application must have the exact sequence listed, without a single nucleotide difference (Office Action of 12/8/05, page 2). Applicants disagree.

The MPEP 706.02(b) states that a rejection based on 35 U.S.C. 102(e) may be overcome by claiming priority to an earlier reference and by establishing that the priority document satisfies the enablement and written description requirements of 35 U.S.C. 112, first paragraph.

To satisfy the written description requirement of 35 U.S.C. 112, ¶ 1, the description must show that the applicant was in possession of the claimed invention at the time of filing. "Possession may be shown in a variety of ways including ...describing distinguishing identifying characteristics" (Guidelines, 66, Fed. Reg. at 1104), "... which provide evidence that the applicant was in possession of the claimed invention, i.e. complete or partial structure..." (id at 1106). The PTO guidelines further point out that based on the language of Eli Lilly 119 F.3d at 1566, which says, "An adequate written description of a DNA requires a precise definition, such as by structure, formula, chemical, name or physical properties." Thus, "there is no basis for... requiring disclosure of complete DNA sequences or limiting DNA claims to only the sequence disclosed" (Guidelines, 66, Fed. Reg. at 1101). Therefore, to obtain an earlier priority date, it is not required that a nucleotide sequence be the identical sequence taught in the earlier application. Applicants demonstrate possession of the currently claimed invention in the priority application by describing a partial structure of the human p-HYDE gene as well as by disclosing its identifying characteristics (hydrophilicity between

specific residues, differential expression in prostate cancer cell lines, apoptosis induction, tumor suppression).

To satisfy the enablement requirement of 35 U.S.C. 112, ¶ 1, an application must disclose the claimed invention in sufficient detail to enable a person of ordinary skill in the art to make and use the claimed invention. The partial human p-HYDE sequence disclosed in the 09/302,457 application (SEQ ID NO: 5) along with the full length rat p-HYDE sequence (SEQ ID NO: 1), a description of the defining characteristics of the p-HYDE gene, and the knowledge in the art that human and rat genes share a certain degree of homology, would enable a person of ordinary skill in the art to make and use the human p-HYDE nucleotide and protein sequences based on the 09/302,457 specification.

Thus, Applicants have shown that the priority document satisfies the enablement and written description requirements of 35 U.S.C. 112, first paragraph. Applicants therefore request withdrawal of the priority rejection.

Sequences

Applicants herein submit a CRF and paper copy of the sequence listing and a statement that the CRF and paper copy are identical. Additionally, Applicants include an alignment of the coding DNA (SEQ ID NO: 3) and amino acid sequence (SEQ ID NO: 7) to clearly show support and the lack of new matter (Appendix 1). Applicants request withdrawal of the objections to the specification in light of the submission of the CRF as described above.

35 U.S.C. 112 1st paragraph rejection

Applicants thank the Examiner for withdrawing objections to the specification and to claims and for withdrawing rejections to claims in light of previous amendments and cancellations.

Claims 1, 7, 10, 11, 18-27, 55, 56, 59, and 60 have been rejected as allegedly failing to comply with the written description requirement. The Examiner alleged that the sequence of the full length human p-HYDE protein has not been disclosed and could not be

predicted by those of skill in the art. Applicants disagree. The partial human p-HYDE sequence disclosed in SEQ ID NO: 1 along with the full length rat p-HYDE sequence disclosed in SEQ ID NO: 3 of the instant invention, together with the knowledge in the art that human and rat genes with similar functions share a high degree of homology and a description of the defining characteristics of the p-HYDE gene (differential expression in prostate cancer cell lines, apoptosis induction, tumor suppression) would enable a person of ordinary skill in the art, using tools available in the Art at the time of the invention (bio-informatic tools, gene expression tools, functional assays) to make and use the human p-HYDE gene.

The Examiner further alleged that claims are drawn to a genus of different sequences that comprise the human p-HYDE of SEQ ID NO: 1 without describing a function, and that a description of at least one species and the common characteristics of the claimed molecules are required to support the genus. Applicants submit that the claims are drawn to a single species (human p-HYDE nt and aa sequence) as opposed to a genus such as any p-HYDE gene.

Applicants note that the Examiner agrees that the claims are enabled.

35 U.S.C. 101 rejection

The Examiner rejected claims 1, 7, 10, 11, 18-27, 55, 56, 59, and 60 because they allegedly lack patentable utility. The Examiner agrees that the p-HYDE gene has patentable utility, but disputes that the disclosed portion of the human p-HYDE gene will necessarily have the same function as the full-length gene. However, Applicants are not claiming a domain of the human p-HYDE protein, but rather are claiming the full-length gene, which is a rat p-HYDE homolog and would be credibly associated with encoding a protein with a similar function as the rat p-HYDE protein, especially in light of the evidence that they are similarly regulated in prostate cancer cells. Therefore, Applicants request withdrawal of the rejection.

35 U.S.C. 102 rejection

In the Office Action, the Examiner rejected claim 55 as allegedly being anticipated by Ni et al (USPAP 2002/0064818). Applicants disagree and maintain that the instant invention should be awarded the priority date of April 29, 1999, as described above, which antedates the September 3, 1999 priority date of Ni et al. Ni et al. is therefore not an appropriate anticipatory reference for the present invention. However, in order to expedite prosecution, Applicants have cancelled claim 55. Accordingly, the rejection is moot.

In view of the foregoing amendments and remarks, the pending claims are deemed to be allowable. Their favorable reconsideration and allowance is respectfully requested.

Should the Examiner have any question or comment as to the form, content or entry of this Amendment, the Examiner is requested to contact the undersigned at the telephone number below. Similarly, if there are any further issues yet to be resolved to advance the prosecution of this application to issue, the Examiner is requested to telephone the undersigned counsel.

Please charge any fees associated with this paper to deposit account No. 50-3355.

Respectfully submitted,

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Appendix I

Comparison of nucleotides from SEQ ID NO: 3 (lower row) and amino acids from SEQ ID NO:7 (upper rows)

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 M   S   G   E   M   D   K   P   L   I   S   R   R   L   V   D   S   D      18
ATG TCC GGG GAG ATG GAC AAA CCG CTC ATC AGT CGC CGC TTG GTG GAC AGT GAT      54

 G   S   L   A   E   V   P   K   E   A   P   K   V   G   I   L   G   S      36
GGC AGT CTG GCT GAG GTC CCC AAG GAG GCT CCC AAA GTG GGC ATC CTG GGC AGC     108

 G   D   F   A   R   S   L   A   T   R   L   V   G   S   G   F   F   V      54
GGG GAT TTT GCC CGG TCC CTG GCC ACA CGC CTG GTG GGC TCT GGC TTC TTT GTG     162

 V   V   G   S   R   N   P   K   R   T   A   G   L   F   P   S   L   A      72
GTG GTG GGA AGC CGT AAC CCC AAA CGC ACT GCC GGC CTC TTC CCC TCC TTA GCC     216

 Q   V   T   F   Q   E   E   A   V   S   S   P   E   V   I   F   V   A      90
CAA GTG ACT TTC CAG GAG GAG GCC GTG AGC TCT CCA GAG GTC ATC TTT GTG GCC     270

 V   F   R   E   H   Y   S   S   L   C   S   L   A   D   Q   L   A   G     108
GTG TTC CGG GAG CAC TAC TCC TCA CTG TGC AGT CTT GCT GAC CAG TTG GCT GGC     324

 K   I   L   V   D   V   S   N   P   T   E   K   E   R   L   Q   H   R     126
AAG ATC CTA GTG GAT GTA AGC AAC CCC ACG GAG AAG GAG CGT CTT CAG CAC CGC     378

 Q   S   N   A   E   Y   L   A   S   L   F   P   A   C   T   V   V   K     144
CAG TCG AAC GCC GAG TAC CTG GCC TCC CTC TTC CCT GCC TGC ACT GTG GTC AAG     432

 A   F   N   V   I   S   A   W   A   L   Q   A   G   P   R   D   G   N     162
GCC TTC AAC GTC ATC TCT GCA TGG GCC CTA CAG GCT GGC CCA AGG GAT GGG AAC     486

 R   Q   V   L   I   C   G   D   Q   L   E   A   K   H   T   V   S   E     180
AGG CAG GTG CTC ATC TGC GGT GAC CAG CTG GAA GCC AAG CAC ACC GTC TCA GAG     540

 M   A   R   A   M   G   F   T   P   L   D   M   G   S   L   A   S   A     198
ATG GCG CGC GCC ATG GGT TTC ACC CCA CTG GAC ATG GGA TCC CTG GCC TCA GCG     594

 R   E   V   E   A   I   P   L   R   L   L   P   S   W   K   V   P   T     216
AGG GAG GTA GAG GCC ATA CCC CTG CGC CTC CTT CCA TCC TGG AAG GTG CCC ACC     648

 L   L   A   L   G   L   S   T   Q   S   Y   A   Y   N   F   I   R   D     234
CTC CTG GCC CTG GGG CTA AGC ACA CAA AGC TAT GCC TAC AAC TTC ATC CGG GAC     702

 V   L   Q   P   Y   I   R   K   D   E   N   K   F   Y   K   M   P   L     252
GTT CTA CAG CCG TAC ATC CGG AAA GAT GAG AAC AAG TTC TAC AAG ATG CCC CTG     756

 S   V   V   N   T   T   I   P   C   V   A   Y   V   L   L   S   L   V     270
TCT GTG GTC AAC ACC ACG ATA CCC TGT GTG GCT TAC GTG CTG CTG TCC CTG GTT     810

 Y   L   P   G   V   L   A   A   A   L   Q   L   R   R   G   T   K   Y     288
TAC CTG CCT GGT GTG CTG GCA GCT GCC CTT CAG CTG AGG AGG GGG ACC AAG TAC     864

 Q   R   F   P   D   W   L   D   H   W   L   Q   H   R   K   Q   I   G     306
CAG CGC TTC CCA GAC TGG CTG GAC CAT TGG CTG CAG CAC CGC AAG CAG ATC GGG     918

 L   L   S   F   F   F   A   M   L   H   A   L   Y   S   F   C   L   P     324
CTA CTC AGC TTT TTT TTC GCC ATG CTG CAC GCT CTC TAC AGC TTC TGC CTG CCG     972

 L   R   R   S   H   R   Y   D   L   V   N   L   A   V   K   Q   V   L     342
CTG CGC CGC TCC CAC CGC TAT GAT CTG GTC AAC CTG GCT GTG AAG CAG GTC CTG    1026
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 A   N   K   S   R   L   W   V   E   E   E   V   W   R   M   E   I   Y     360
GCC AAC AAG AGC CGC CTC TGG GTT GAG GAA GAA GTC TGG CGG ATG GAG ATA TAC   1080

 L   S   L   G   V   L   A   L   G   M   L   S   L   L   A   V   T   S     378
CTG TCC CTG GGT GTG CTG GCT CTG GGC ATG CTG TCA CTG CTG GCG GTT ACC TCG   1134

 I   P   S   I   A   N   S   L   N   W   K   E   F   S   F   V   Q   S     396
ATC CCT TCC ATT GCA AAC TCA CTC AAC TGG AAG GAG TTC AGC TTT GTG CAG TCC   1188

 T   L   G   F   V   A   L   M   L   S   T   M   H   T   L   T   Y   G     414
ACG CTG GGC TTC GTG GCC CTG ATG CTG AGC ACA ATG CAC ACC CTC ACC TAC GGC   1242

 W   T   R   A   F   E   E   N   H   Y   K   F   Y   L   P   P   T   F     432
TGG ACC CGT GCT TTT GAG GAA AAC CAC TAC AAG TTC TAC CTG CCA CCC ACA TTC   1296

 T   L   T   L   L   L   P   C   V   I   I   L   A   K   G   L   F   L     450
ACG CTC ACG CTG CTC CTG CCC TGT GTC ATC ATC CTG GCC AAG GGC CTC TTC CTC   1350

 L   P   C   L   S   H   R   L   T   K   I   R   R   G   W   E   R   D     468
CTG CCC TGC CTC AGC CAC AGA CTC ACC AAG ATC CGC AGG GGC TGG GAG AGG GAT   1404

 G   A   V   K   F   M   L   P   A   G   H   T   Q   G   E   K   T   S     486
GGT GCC GTC AAG TTC ATG CTG CCC GCT GGC CAC ACA CAG GGG GAG AAA ACA AGC   1458

 H   V   *                                                               489
CAC GTG TGA                                                             1467
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